



Medtronic

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August 20, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 99N-1737; Notice – Public Availability of Information on Clinical Trials for Investigational Devices Intended to Treat Serious or Life-Threatening Conditions

To Whom It May Concern:

These comments are submitted by Medtronic in response to the Food and Drug Administration's notice (64 FR 33313 - June 22, 1999) concerning the feasibility of including information about clinical trials of investigational devices in a public database.

The Health Industry Manufacturer's Association, HIMA, has responded to the FDA notice on behalf of the medical device companies constituting its membership. We agree in principle with those comments and wish to stress some additional points of specific concern to Medtronic. In particular, we believe that FDA should heed the direction established in the act to wait for a period of time after the establishment of the database for drug trials before initiating a similar database for medical devices.

In general, Medtronic believes that there are times when it would be in the interest of the public health to make information about on-going trials available to those in need of medical device therapies. However, we believe that the public health interest would be best served if the information to be disseminated related only to those studies of devices that treat conditions for which there are no approved alternative therapies. This would represent only a fraction of the studies being conducted under the IDE at any one time. We are concerned that the inclusion of all IDEs would place additional burden on all study centers to respond to requests for information while not creating benefit for patients.

Medtronic considers the information contained in the investigational plans for its clinical studies to be proprietary, including the inclusion and exclusion criteria and the indications for use. This information, if made available to the public, would provide valuable insight to our competitors regarding our regulatory and clinical strategies for new products. Also, disclosing this type of information to the general public would not help patients determine their suitability as study participants.

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When Life Depends on Medical Technology

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FDA should look for other avenues by which to disseminate this information if it decides to proceed. For example, information that is disseminated could be made available only to qualified health professionals rather than the general public. This would allow someone who understands the medical implications of the study and the therapeutic needs of a particular patient to make a determination of whether or not the device being studied in the trial might offer some benefit to that patient.

In summary, Medtronic believes there might be some public health benefit from making information available to the medical community on clinical studies of devices that treat conditions for which there are no alternative therapies. However, FDA should seek methods other than release to the general public and any information that is released must not compromise the competitive position of the study sponsor.

FDA should see what the results of the proposed drug trial database are before proceeding with a device database. The experience with drug studies could provide valuable insight into the feasibility of a similar database for devices.

Medtronic appreciates the opportunity to comment on this issue.

Sincerely,

A handwritten signature in cursive script, appearing to read "C. Whitacre".

Chip Whitacre
Director, Corporate Regulatory and
Clinical Affairs
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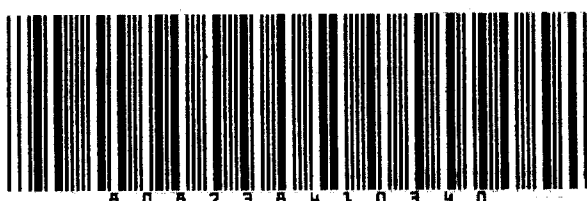
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